

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

MARK M. ZANECKI,

Plaintiff,

v.

Case No. 12-13233

District Judge Nancy G. Edmunds
Magistrate Judge Laurie J. Michelson

HEALTH ALLIANCE PLAN OF DETROIT -
INSTITUTIONAL REVIEW BOARD, et al.,

Defendants.

**REPORT AND RECOMMENDATION TO GRANT HENRY FORD HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD #1'S MOTION TO DISMISS [47] AND TO
DENY WITHOUT PREJUDICE ST. JOSEPH MERCY OAKLAND - TRINITY HEALTH
SYSTEM INSTITUTIONAL REVIEW BOARD #1'S
MOTION FOR SUMMARY JUDGMENT [9]**

In 2007, Richard Zanecki, then 82 years old, suffered a mini-stroke and underwent a surgical procedure involving the use of a certain wingspan stent. (Dkt. 38, Am. Compl. ¶¶ 50, 51.) He died a few days later. (Am. Compl. ¶ 250.) Plaintiff Mark Zanecki is Richard Zanecki's son and the executor of his estate. (Am. Compl. ¶ 9, Dkt. 9, St. Joseph IRB's Mot. Summ J., Ex. F, Jan 18, 2011 Mark Zanecki Aff. ¶ 1.) Almost five years after his father's death, Plaintiff filed this suit asserting that two institutional review boards, Defendants St. Joseph Mercy Oakland - Trinity Health System IRB #1 ("St. Joseph IRB") and Henry Ford Health System IRB #1 ("Henry Ford IRB"), contributed to his father's death by, among other things, wrongly "authoriz[ing] procurement and performance of Wingspan stent procedures." (Am. Compl. ¶ 242.) Before the Court for a report and recommendation (Dkt. 10) are St. Joseph IRB's Motion for Summary Judgment (Dkt. 9) and Henry Ford IRB's Motion to Dismiss (Dkt. 47). The Court has reviewed Plaintiff's lengthy responses to both motions (Dkts. 44, 49) as well as his 183-page Amended Complaint (Dkt. 38). Upon careful

consideration of the parties' arguments and Plaintiff's allegations, the Court believes that oral argument will not significantly aid in the resolution of the pending motions. *See* E.D. Mich. LR 7.1(f). For the reasons that follow, this Court recommends that Henry Ford IRB's motion be GRANTED and that St. Joseph IRB's motion be DENIED WITHOUT PREJUDICE.

I. BACKGROUND

A. Factual Background

On September 28, 2007, Richard Zanecki suffered a minor transient ischemic attack, i.e., blood did not flow to part of his brain for a brief period. (Am. Compl. ¶ 50.) He was initially treated at St. Joseph Mercy Oakland Hospital. (*Id.* ¶ 51.) While there, Richard Zanecki's treating physician recommended that he undergo a procedure involving a Boston Scientific Wingspan Stent ("Wingspan Stent"): a medical device capable of opening a clogged cerebral blood vessel. (*See Id.* ¶¶ 51, 65.) Three days after the procedure, on October 3, 2007, Richard Zanecki died. (*Id.* ¶¶ 48, 250.)

In November 2009, Richard Zanecki's estate brought a medical malpractice suit in state court against certain physicians, an employer of one of the physicians, and Trinity Health – Michigan d/b/a as St. Joseph Mercy Oakland asserting, that they, among other things, committed medical malpractice and failed to obtain adequate informed consent before performing the Wingspan Stent procedure. (*See* St. Joseph IRB's Mot. Summ J., Ex. A, Oakland County Cir. Ct. Compl.) That case resulted in a monetary settlement. (St. Joseph IRB's Mot. Summ J., Ex. B, Settlement Agreement; *see also id.*, Ex. F, Jan 18, 2011 Mark Zanecki Aff. ¶ 10.)

On July 23, 2012, almost five years after Richard Zanecki's death and more than a year-and-a-half after the state-court settlement, Mark Zanecki ("Zanecki"), proceeding *pro se*, filed this case

against two institutional review boards: St. Joseph IRB and Henry Ford IRB. Neither St. Joseph IRB nor Henry Ford IRB were named in the state-court case.

Institutional review boards are responsible for protecting the rights and welfare of human subjects in biomedical research. 21 C.F.R. § 56.102(g). Regulations promulgated by the Food and Drug Administration (“FDA”) provide that an IRB “means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects.” *Id.* The regulations set forth requirements for IRB membership and provide that each IRB must have the ability to “ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards o[f] professional conduct and practice.” 21 C.F.R. § 56.107; *see also* (Am. Compl. ¶¶ 78, 80, 81). Accordingly, IRBs have a number of responsibilities, including, “review[ing] and hav[ing] authority to approve, requir[ing] modifications in (to secure approval), or disapprov[ing] all research activities covered by [the FDA IRB] regulations.” 21 C.F.R. § 56.109; *see also* 20 C.F.R. § 56.108; (Am. Compl. ¶ 131). Plaintiff asserts that for the period January 1, 2006 through December 2007, St. Joseph IRB designated Henry Ford IRB to be the “authoritative internal review board . . . for approval and oversight of clinical research involving human subjects for St. Joseph Mercy Oakland Hospital.” (Am. Compl. ¶ 156; *see also id.* ¶ 144.)

Plaintiff alleges that since August 2005, the Boston Scientific Wingspan Stent was approved by the FDA under a limited “humanitarian device exemption.” (Am. Compl. at 49.) Congress has provided that devices approved under the humanitarian device exemption may only be used in facilities that have established an IRB “to supervise clinical testing of devices,” and where, absent an emergency situation, the IRB has approved the use of the device for the treatment of a rare

condition (one affecting fewer than 4,000 people in the United States). 21 U.S.C. § 360j(m)(4); *see also* 21 C.F.R. § 814.124 (providing that “a [humanitarian use device] may be administered only if such use has been approved by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use . . .”).

Thus, the gravamen of Plaintiff’s 183-page Amended Complaint appears to be that Defendants St. Joseph IRB and Henry Ford IRB, in contravention to federal law, including IRB and Medicare regulations, “acted to approve” the Wingspan Stent enabling its “procurement.” (Am. Compl. ¶ 100; *see also* Am. Compl. ¶¶ 161, 188-90 (citing IRB duties under 21 C.F.R. § 56.111(a)).) And, according to Plaintiff, this procurement “enabled” Wingspan Stent procedures to take place at St. Joseph Mercy Oakland Hospital between October 24, 2006 and December 2007. (Am. Compl. ¶ 100.) He continues, “But for [the] approval by [St. Joseph IRB] and [Henry Ford IRB] . . . Richard M. Zanecki’s Wingspan procedure of September 30, 2007 would never have occurred and Richard M. Zanecki would be alive today as [he] would have elected Medicare covered therapeutic standard of care . . . in lieu of [the] Wingspan [S]tent [procedure].” (Am. Compl. ¶ 100.) Plaintiff alleges that Defendants’ conduct abridged Richard Zanecki’s federal constitutional rights; his rights under the Medicare Act, its implementing regulations at Title 42 of the Code of Federal Regulations, and the Centers for Medicare & Medicaid Services State Operations Manual; and FDA IRB regulations at Title 21, Part 56 of the Code of Federal Regulations. (Am. Compl. at 42-43; *see also id.* ¶¶ 239-334.) (Plaintiff additionally alleges violations of Michigan law, which, as explained below, have been dismissed. (*See* Am. Compl. at 42-43.))

B. Procedural History

On July 23, 2012, Plaintiff filed a 89-page complaint naming Henry Ford IRB and St. Joseph IRB, as well as Health Alliance Plan of Detroit – Institutional Review Board and the individual members of Henry Ford IRB and St. Joseph IRB. (Dkt. 1.) About two weeks later, Plaintiff filed a motion for leave to amend his complaint. (Dkt. 3.) He suggested to the Court that the amendments would be limited: he would dismiss the individual IRB members and Health Alliance Plan of Detroit - Institutional Review Board (and, thereby, assert claims against only St. Joseph IRB and Henry Ford IRB), and he would add information based on recent Freedom of Information Act (“FOIA”) responses. (Dkt. 3.)

On August 13, 2012, District Judge Nancy G. Edmunds issued an order dismissing Plaintiff’s state-law claims and exercising jurisdiction over only Count IV of Plaintiff’s original complaint — a count brought pursuant to 42 U.S.C. § 1983 and alleging that the IRBs violated Richard Zanecki’s constitutional right to liberty and right to refuse medical care. (Dkt. 4, Order of Dismissal as to Plaintiff’s State Law Claims; *see also* Dkt. 1, Compl. at 78-79.) On the same day, Judge Edmunds granted Plaintiff’s motion for leave to amend.

As of September 25, 2012, however, Plaintiff had not filed an amended complaint, and so this Court directed Plaintiff to “file an Amended Complaint as to Count IV within seven (7) days of this Order.” (Dkt. 24, Order Striking Pl.’s Resp. to St. Joseph IRB’s Mot. Summ. J.) In objecting to this order, Plaintiff noted that his reasons for seeking leave to amend included (1) “naming of Defendant parties as internal review board as a group, rather than as individual members as in original complaint,” (2) making “required edits due to dismissal of state based claims and retaining only Count IV, civil rights allegations,” and (3) filing “voluminous exhibits to meet requirements

of Fed.R.Civ.P. Rule 4.” (Dkt. 25, Pl.’s Objs. to Order Striking Pl.’s Resp. to St. Joseph IRB’s Mot. Summ. J. at Pg ID 3539.)

On October 22, 2012, Plaintiff filed an Amended Complaint that is nearly 100 pages longer than the original complaint. (*See generally* Dkt. 38, Am. Compl.) It also includes thousands of pages in exhibits. (Dkts. 26-37.) Further, Plaintiff added several counts that do not readily appear to be recognized causes of action, let alone claims based on Richard Zanecki’s constitutional right to liberty and right to refuse medical care. (*See* Am. Compl. Counts I, II, V, VI.)¹

II. ANALYSIS

A. Legal Standard

In reviewing a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court must “construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff,” but the Court “need not accept as true legal conclusions or unwarranted factual inferences.” *Hunter v. Sec’y of U.S. Army*, 565 F.3d 986, 992 (6th Cir. 2009) (quoting *Jones v. City of Cincinnati*, 521 F.3d 555, 559 (6th Cir. 2008)). To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead “sufficient factual matter” to “state

¹As the Court has undoubtedly made clear, the Amended Complaint is not the type of “short and plain statement” contemplated by the Federal Rules. *See* Fed. R. Civ. P. 8. The Court adds that Plaintiff’s response briefs do not comply with the font-size requirements (too small) or the line-spacing requirements (excessive single spacing) set forth in the local rules. *See* E.D. Mich. LR 5.1(a)(2), (3). Plaintiff’s briefs are therefore much longer than those permitted by the local rules. *See* E.D. Mich. 7.1(d)(3).

The Court has already struck one of Plaintiff’s briefs filed in this case. (*See* Dkt. 24, Order Striking Pl.’s Resp. to St. Joseph IRB’s Mot. Summ. J.) In doing so, this Court “urge[d] Plaintiff to familiarize himself with the Federal and Local Rules and expect[ed] that future filings will comply with those Rules.” *Id.* For the last time, the Court warns Plaintiff that even pro se briefs, motions, or pleadings must comply with Federal Rules and Eastern District of Michigan Local Rules. A failure to comply will result in papers being stricken.

a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* The plausibility standard is not a “probability requirement,” but it does require “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* at 679.

B. The Statute of Limitations Bars Plaintiff’s Suit

Henry Ford IRB’s lead argument is that the claims in Plaintiff’s Amended Complaint are barred by the statute of limitations associated with 42 U.S.C. § 1983 claims. (Henry Ford IRB’s Mot. to Dismiss at 4-6.) The parties agree that a three-year statute of limitation, borrowed from state law, applies to § 1983 claims arising in Michigan. (*Compare* Henry Ford IRB’s Mot. to Dismiss at 4-5 *with* Pl.’s Resp. to Henry Ford IRB’s Mot. to Dismiss at 7); *see also Drake v. City of Detroit, Michigan*, 266 F. App’x 444, 448 (6th Cir. 2008); *Owens v. Okure*, 488 U.S. 235, 240-41 (1989). They also agree that federal law governs when the claim accrued. (*Compare* Henry Ford IRB’s Mot. to Dismiss at 5 *with* Pl.’s Resp. to Henry Ford IRB’s Mot. to Dismiss at 7); *see also Roberson v. Tennessee*, 399 F.3d 792, 794 (6th Cir. 2005).

The lone dispute is over the accrual date. Plaintiff asserts that the accrual date is the date the state-court action was filed:

[t]here can be no dispute that accrual date could not be earlier than November 13, 2009 filing of Medical Malpractice complaint. The statute of limitations running 3 years from November 13, 2009 is November 13, 2012. This Complaint was filed on July 23, 2012 and is timely filed.

(Pl.’s Resp. to Henry Ford IRB’s Mot. to Dismiss at 7.) But, as this statement makes plain, Plaintiff offers no explanation for why the accrual date is, at earliest, when Richard Zanecki’s estate initiated the state-court action. (*See id.*) And federal law is to the contrary.

“Under federal law, as developed in this Circuit, the statute of limitations period begins to run when the plaintiff knows or has reason to know that the act providing the basis of his or her injury has occurred.” *Collyer v. Darling*, 98 F.3d 211, 220 (6th Cir. 1996); *Sevier v. Turner*, 742 F.2d 262, 273 (6th Cir. 1984). Stated differently, “[i]n determining when the cause of action accrues in § 1983 cases, we look to the event that should have alerted the typical lay person to protect his or her rights.” *Trzebuckowski v. City of Cleveland*, 319 F.3d 853, 856 (6th Cir. 2003). The Court must therefore look at when the harm in question occurred, guided by the principle that “[a] plaintiff has reason to know of his injury when he should have discovered it through the exercise of reasonable diligence.” *Sevier*, 742 F.2d at 273.

In this case, the injuries alleged — Richard Zanecki’s pain, suffering, and death, as well as the Zanecki family’s emotional distress and loss of consortium (*e.g.*, Am. Compl. ¶ 296) — stem directly from Richard Zanecki’s death on October 3, 2007. Plaintiff offers no explanation as to why he did not have reason to know of these injuries until Richard Zanecki’s estate filed the state-court complaint on November 13, 2009. And without explanation, the date appears entirely arbitrary. Indeed, in his Amended Complaint, Plaintiff, then operating under the belief that a six-year statute of limitations applied to actions brought pursuant to 42 U.S.C. § 1983, alleged the accrual date was October 3, 2007. (Am. Compl. ¶ 3.) Accordingly, the Court believes that Plaintiff’s claim accrued on October 3, 2007, and that the statute of limitations period expired on October 3, 2010. Plaintiff’s suit was therefore filed almost two years too late.

To the extent that Plaintiff would argue that he did not know that Henry Ford IRB and St. John IRB were involved in Richard Zanecki's death, such an argument would not require a different result. At the time of Richard Zanecki's death, or very shortly thereafter, Plaintiff knew, or through reasonable diligence, could have determined that the Boston Scientific Wingspan Stent was used in Richard Zanecki's angioplasty. (*See* Am. Compl. ¶ 51.) With that fact, Plaintiff could have determined that the FDA approved the device under a limited humanitarian device exemption. This in turn, would have led Plaintiff to the very claims he makes now: that institutional review board approval was necessary before the Wingspan Stent was procured, and Henry Ford IRB and St. John IRB violated their review-board obligations in approving use of the Wingspan Stent and/or failing to ensure that Richard Zanecki was provided with proper informed consent. Moreover, precedent provides that Plaintiff did not need to know the specific identity of the potential defendant before his claim would accrue. *See Dyniewicz v. United States*, 742 F.2d 484, 486 (9th Cir. 1984) ("Discovery of the cause of one's injury, however, does not mean knowing who is responsible for it."); *Staves v. City of L.A.*, No. 10-00967, 2010 U.S. Dist. LEXIS 72824, *8 (June 15, 2010) *report and recommendation adopted by* 2010 U.S. Dist. LEXIS 72828 (C.D. Cal. July 19, 2010) (finding that "contrary to Plaintiff's contention, his claim accrued when he knew of both his injury and its cause, not when he learned the identity of the individual defendants. The Ninth Circuit has consistently found that a plaintiff need not know the identity of the person who caused his injury in order to trigger the statute of limitations."); *Bush v. Hutchenson*, No. 12-336, 2012 U.S. Dist. LEXIS 70101 *12-13, n.2 (W.D. Mich. May 21, 2012) ("Plaintiff's claim based on his 2005 treatment accrued at that time because he had reason to know of the 'harms' done to him at the time they occurred. Plaintiff, however, did not file his complaint until April 2012, well past Michigan's three-

year limit.”).²

Finally, although Plaintiff has made no argument to the contrary, the Court makes explicit what is implicit throughout Plaintiff’s Amended Complaint and his response to Henry Ford IRB’s motion: that every count in Plaintiff’s Amended Complaint is based on 42 U.S.C. § 1983. Beginning with the Amended Complaint, Plaintiff says that “this Court has original jurisdiction pursuant to 28 U.S.C. § 1331, *in that* certain counts raise federal questions under 42 U.S.C. § 1983.” (Am. Compl. ¶ 1 (emphasis added).) The Court understands this statement to mean that it has federal-question jurisdiction “in that,” i.e., “because” Plaintiff has brought his claims under § 1983. While the word “certain” implies that some claims may not be premised on § 1983, the implication is not strong: each count in the Amended Complaint includes a paragraph stating, “[a]t all relevant times, Defendants were acting under color of state law as state actors.” (Am. Compl. ¶¶ 240, 254, 272, 286, 300, 314.) Moreover, Plaintiff spent nearly 20 pages of his Amended Complaint alleging and arguing that Defendants are state actors under the public function or joint participation test. (Am. Compl. at 25-41, 47-49.) Based on just the Amended Complaint, therefore, it is likely that Plaintiff intended to plead all counts under 42 U.S.C. § 1983.

The inference is strengthened upon review of Plaintiff’s response to Henry Ford IRB’s Motion to Dismiss. Henry Ford IRB’s entire motion is premised on the assumption that each claim in Plaintiff’s Amended Complaint is brought pursuant to § 1983. Henry Ford IRB could not have

²Plaintiff makes no equitable tolling argument. The Court notes that in paragraph 200 of his Amended Complaint he asserts that he received a FOIA response after the state-court case settled, and that the response supports an “uncontrolled secret” Wingspan Stent clinical trial. (Am. Compl. ¶ 200.) But this new information would not justify equitable tolling given that Plaintiff pleads he did not even make the FOIA request until December 29, 2010 — more than three years after Richard Zanecki’s death. (*Id.*)

made this clearer to Plaintiff. It asserted – and not unreasonably in light of Judge Edmunds’ initial ruling on the original complaint – that “the single remaining basis of liability is 42 U.S.C. § 1983” and that the Amended Complaint is “neither timely nor sufficient to set forth a claim under 42 U.S.C. § 1983.” (Henry Ford IRB’s Mot. to Dismiss at 2, 4.) Further, underlying every one of Henry Ford IRB’s arguments is the understanding that Plaintiff brought all of his claims pursuant § 1983.³ Yet, in responding to Henry Ford IRB’s motion, Plaintiff does not challenge Henry Ford IRB’s assumption.

Strongest though, are Plaintiff’s explicit statements in his response to Henry Ford IRB’s motion. He states, “In this action, brought under 42 U.S.C. § 1983, U.S. Constitution, Plaintiff challenges authoritative of St. Joseph Mercy Oakland Hospital and authoritative IRB for HAP approval of Wingspan Stent and ‘use’ on human subjects” (Pl.’s Resp. to Henry Ford IRB’s Mot. to Dismiss at 4.) Elsewhere, Plaintiff asserts that Henry Ford IRB is “a state actor” that has violated “clearly established Constitutional Rights recognized by the U.S. Supreme Court and Medicare Rights” and is “thus subject to liability under 42 U.S.C. [§] 1983.” (*Id.* at 13.) He also says that St. Joseph IRB and Henry Ford IRB “each act[ed] under color of state law and each are state actors . . . and are thus subject to complaint under 42 U.S.C. § 1983 for violations of rights granted under U.S. Constitution and federal law (Medicare).” (*Id.* at 1-2.) Finally, in concluding

³In particular, Henry Ford IRB asserts that (1) Plaintiff’s claims are time-barred under the three-year statute of limitations applicable to § 1983 actions arising in Michigan, (2) Henry Ford IRB was not acting under the color of state law, (3) Counts I, II, V, and VI allege rights not enforceable under § 1983, (4) Counts III and IV do not state a claim because there are adequate post-deprivation remedies under the *Parratt-Hudson* doctrine and because there is no respondeat superior liability under § 1983, (5) Henry Ford IRB is entitled to qualified immunity, and (6) § 1983 claims are personal to Richard Zanecki and damages cannot be based on harm to Richard Zanecki’s family. (Henry Ford IRB’s Mot. to Dismiss at 4-24.)

his response to Henry Ford IRB's motion, Plaintiff says, "For the above stated reasons, argument and cited authorities[,] Plaintiff's First Amended Complaint sets forth a valid cause or action under 42 U.S.C. § 1983 and U.S. Constitution, the [F]ifth and [F]ourteenth [A]mendments[,] and thus[,] [Henry Ford IRB] failed to meet [its] burden for dismissal or summary judgment" (*Id.* at 21.)

Accordingly, the Court believes that Plaintiff has brought all claims in this suit pursuant to 42 U.S.C. § 1983. It follows that Plaintiff's Amended Complaint is barred by a three-year statute of limitations, and that dismissal is warranted on this basis.

C. Plaintiff Has Not Adequately Pled How The Medicare Standards Apply to Defendants and the Cited Institutional Review Board Regulations Do Not Create a Private Right of Action

Out of an exercise of caution, the Court offers the following alternative bases for dismissing Counts I, II, V, and VI. (Counts III and IV allege violations of the federal constitution, and, therefore, Plaintiff cannot in good faith object that he did not bring those two counts pursuant to 42 U.S.C. § 1983.)

Counts I, V, and VI are premised in whole, and Count II is premised in part, on alleged violations of Medicare regulations and Centers for Medicare & Medicaid Services' ("CMS") guidelines, manuals, and National Coverage Decisions. The Court has reservations as to whether Plaintiff may bring a private right of action under the Medicare regulations he cites (e.g., 42 C.F.R. §§ 411.406, 405.211), let alone the cited CMS interpretative guidelines for certain Medicare regulations (e.g., 42 C.F.R. § 482.13(b)(2), (c)(3)). *See Smith v. Univ. of Minn. Med. Ctr.-Fairview Riverside*, No. 09-293, 2010 WL 3893902, at *16 (D. Minn. July 14, 2010) *report and recommendation adopted*, 2010 WL 3893849 (D. Minn. Sept. 30, 2010) ("The regulation 42 C.F.R. § 482.13 provides that hospital patients have the right to receive notice of their rights, to be involved

in the planning of their healthcare, to make informed decisions, to privacy and confidentially, to be free of physical and mental abuse (including the right to be free of restraint and seclusion unless necessary), and to a grievance process set up by the hospital. Nothing in this regulation provides for a private cause of action. Further nothing in the text of the statute authorizing the regulation, 42 U.S.C. § 1396hh, suggests any right to a private cause of action to enforce the regulations set forth at § 482.13. On this [alternative] basis, this Court finds that even if [Plaintiff] had not abandoned this claim, 42 C.F.R. § 482.13 can provide him with no relief.” (footnote omitted)); *Hinojosa v. Perez*, 214 F. Supp. 2d 703, 705 (S.D. Tex. 2002) (“42 C.F.R. § 482.12 sets forth requirements regarding medical staff, management, patient care, budgeting, contracting, and emergency services for hospitals receiving funds through the Medicare program. Nowhere does it reference a private right of action to enforce these requirements.”); *Brogdon ex rel. Cline v. Nat’l Healthcare Corp.*, 103 F. Supp. 2d 1322, 1330 (N.D. Ga. 2000) (“The great majority of courts have determined that the Medicare and Medicaid Acts do not authorize private causes of action against nursing homes.”). But making this determination is not necessary in this case. While citing numerous standards set forth by the Medicare regulations or CMS, Plaintiff has not adequately pled how these standards apply to these particular Defendants — two institutional review boards. In other words, even assuming that Plaintiff could bring a claim for violations of the cited Medicare regulations or CMS interpretive guidelines, Plaintiff has not adequately pled how these particular Defendants violated those standards.

In Count I, Plaintiff cites a September 7, 2007 CMS National Coverage Determination (“NCD”), in part providing that

CMS, through the NCD process, through an individualized assessment of benefits, risks, and research potential, may determine

that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

CMS Manual System, Pub. 100-03 Medicare National Coverage Determinations, Transmittal 74 at Part I.B (Sept. 7, 2007), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R74NCD.pdf>; *see also* (Am. Compl. ¶ 242). Plaintiff also cites a November 6, 2006 CMS Decision Memo and a January 5, 2007 NCD that allegedly provide that the Wingspan Stent is “reasonable and necessary,” and a Medicare-covered benefit, only for those with artery stenosis greater than 50% and who are refractory to other treatment. (Am. Compl. ¶ 242.) Plaintiff then appears to assert that pursuant to their “on-going review responsibilities” under 42 C.F.R. §§ 411.406, 405.211, Defendants knew or should have known that Richard Zanecki’s Wingspan Stent procedure was not a Medicare-covered benefit. (*See* Am. Compl. ¶¶ 242.)

Plaintiff has not adequately pled how these Medicare standards apply to Defendants. 42 C.F.R. § 411.406(a) applies to “provider[s], practitioner[s], [and] supplier[s]” and Plaintiff has not pled how institutional review boards — as opposed to their associated hospital — fall within the regulation’s definitions of those terms. *See* 42 C.F.R. § 400.202 (defining “supplier” as “a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare,” and defining “provider” as “a hospital, a [critical access hospital], a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar

agreement but only to furnish partial hospitalization services.”). Similarly, 42 C.F.R. § 405.211 provides that “Medicare contractors are bound by the statute, regulations, and all CMS administrative issuances, including all national coverage decisions,” and Plaintiff has not adequately pled that institutional review boards are “Medicare contractors.” And, as Plaintiff himself acknowledges (Am. Compl. ¶ 242), NCDs are binding on carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, administrative law judges, and Medicare advantage organizations. 20 C.F.R. § 405.1060(a). Plaintiff has not adequately pled how institutional review boards fall within the statutory definitions of these terms. 20 C.F.R. § 405.902 (defining, for example, a qualified independent contractor as “an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.”).

In Count I, Plaintiff also cites section 50.2.1 of Chapter 13 of the Medicare Managed Care Manual (Am. Compl. ¶ 242) for the proposition that the medical exigency standard “requires that the Medicare health plan or the independent entity apply, at a minimum, established accepted standards of medical practice in assessing an individual’s medical condition,” CMS Manual System, Pub. 100-16 Medicare Managed Care, Transmittal 80, (Mar. 3, 2006), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R80MCM.pdf>. But institutional review boards are not a “Medicare health plan” and the Medicare Managed Care Manual itself defines “independent entity” as an “entity contracted by CMS to review Medicare health plans’ adverse reconsiderations of organization determination.” *Id.* Plaintiff has not pled facts that St. John IRB or Henry Ford IRB have a contract with CMS, let alone that they have a contract to review a Medicare health plans’ “adverse reconsiderations of organization determination.”

Counts II, V, and VI rely on the CMS State Operations Manual to establish that Defendants had certain duties: a duty to obtain a proper informed consent form (Am. Compl. ¶ 256), a duty to ensure that hospital patients are free from abuse (Am. Compl. ¶ 302), a duty to ensure that patients receive care in a safe setting (Am. Compl. ¶ 316), and a duty to ensure appropriate “nuclear medicine” equipment (Am. Compl. ¶ 316). But again, Plaintiff has not adequately pled how these particular *Medicare*-related duties apply to *institutional review boards* such as Defendants. And any inference to that effect is strained. For one, the part of the State Operations Manual Plaintiff cites is “Appendix A - Survey Protocol, Regulations and Interpretive Guidelines *for Hospitals*.” (Am. Compl. ¶¶ 256, 302, 316, Ex. 131 (emphasis added).) Further, some of the portions of the State Operations Manual Plaintiff cites evidence that its standards do not apply to institutional review boards. For example, Plaintiff cites § 482.13(c)(3) and says that “Defendants deprived Richard M. Zanecki of his Medicare patient right to be free from abuse” (Am. Compl. ¶¶ 302, 307); but that provision provides, “[t]he hospital must ensure that patients are free from all forms of abuse, neglect, or harassment. The hospital must have mechanisms/methods in place that ensure patients are free from all forms of abuse, neglect, or harassment,” (Am. Compl. Ex. 131 at Pg ID 5196) (emphases added). As another example, Plaintiff cites § 482.53 of the State Operations Manual to support his claim that Defendants had an obligation to ensure that Richard Zanecki received care in a safe setting, including, an obligation to ensure that equipment was appropriate for “nuclear medicine services.” (Am. Compl. ¶ 316.) But that interpretative guideline provides that “[t]he hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish services offered by the hospital in accordance with acceptable standards of practice.” (Am. Compl. Ex. 131 at Pg ID 5248 (emphasis added).)

To the extent that Plaintiff would now assert that Defendants are considered part of the hospital or are agents of the hospital (to then argue that the Medicare standards apply to Defendants) the Court notes that he has pled to the contrary. The Amended Complaint avers, “Defendant St. Joseph Mercy Oakland Hospital – Trinity Health System IRB#1 is an independent committee comprised of private contractors and not an agent (Restate (Second) of Agency) of St. Joseph Mercy Oakland Hospital.” (Am. Compl. ¶ 81.) Similarly, Plaintiff claims, “Defendant Henry Ford Health System IRB#1 is an independent committee comprised of private contractors and not an agent (Restate (Second) of Agency) of St. Joseph Mercy Oakland Hospital.” (*Id.* ¶ 84.) He also provides that it was HAP Senior Plus that “authorized [the] Wingspan Stent procedure for Richard M. Zanecki on September 30, 2007” and that it was St. Joseph Mercy Oakland Hospital that created the claim form on October 16, 2007 and submitted it for reimbursement to HAP Senior Plus. (Am. Compl. ¶ 52; *see also* Am. Compl. ¶ 235 (asserting that recent FOIA request responses state that “HAP is responsible and maintains all authority for referrals, that HAP is responsible and maintains all authority for utilization control management protocols , require subcontractors to comply with federal, state, local laws and Medicare Act, is responsible to CMS for all sub-contractors under Medicare.”).)

Accordingly, Plaintiff has not adequately pled how these Defendants, St. John IRB or Henry Ford IRB, have violated the Medicare regulations or the CMS standards he cites.

In addition to Medicare standards, Count II also relies on 21 C.F.R. § 50, which, in tandem with 21 C.F.R. § 56.111(a), sets forth a duty on IRBs to determine that proper informed consent will

be sought from each research subject. (Am. Compl. ¶ 263.)⁴ Unlike the Medicare standards Plaintiff relies on, Part 56 of Title 21 of the Code of Federal Regulations does in fact regulate institutional review boards. *See* 20 C.F.R. § 56.101 (“This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration . . .”). But these regulations implementing the Federal Food, Drug, and Cosmetic Act (“FDCA”), including 21 C.F.R. § 50 and 21 C.F.R. § 56.111, do not create a private cause of action. *See Keller v. Strauss*, No. 1:10-CV-3282, 2011 WL 2470631, at *6 (N.D. Ga. June 17, 2011) *aff’d*, 480 F. App’x 552 (11th Cir. 2012) (“Under his medical negligence count, Plaintiff also asserts a violation of 21 C.F.R. § 50.20, an informed consent regulation promulgated under the FDCA. . . . However, neither the FDCA or its regulations support a private right of action.”); *Guckin v. Nagle*, 259 F. Supp. 2d 406, 412 (E.D. Pa. 2003) (holding, in remanding claim to state court for lack of subject-matter jurisdiction, that “[Defendant] has neither argued nor shown that the FDCA, or any relevant, related regulations provide for a private, federal cause of action.”); *see also Keller v. Strauss*, 480 F. App’x 552, 554 (11th Cir. 2012) (“In no situation does the FDCA provide for a private cause of action.”); *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (“Considering the FDCA’s legislative history as set out above, we are compelled to conclude that Congress did not intend, either expressly or by

⁴Elsewhere in the Amended Complaint, Plaintiff also alleges that 21 C.F.R. § 56.111(a) sets forth five duties of care that Defendants have violated through their approval of the Wingspan Stent: (1) ensuring that risks to subjects are minimized (Am. Compl. ¶ 161); (2) ensuring that risks of subjects are reasonable in relation to anticipated benefits (Am. Compl. ¶ 188); (3) ensuring that the selection of research subjects is equitable (Am. Compl. ¶ 191); (4) ensuring that informed consent from each subject has been sought in accordance with 21 C.F.R. § 50 (Am. Compl. ¶ 190); and (5) ensuring that informed consent will be documented in accordance with 21 C.F.R. § 50.27 (Am. Compl. ¶ 190).

implication, to create a private cause of action under the FDCA.”).⁵

Plaintiff also purports to allege, in several counts, that St. Joseph IRB acted under a conflict of interest in approving use of the Wingspan Stent because Jack Weiner, Pharm. D., was chairman of St. Joseph IRB but also President of St. Joseph Mercy Oakland Hospital and CEO of the Michigan Stroke Network (a Trinity Health – Michigan sub-corporation). (Am. Comp. ¶ 45; *see also id.* ¶¶ 229, 275, 277, 291, 305, 325.) Plaintiff says that “members would be influenced directly or indirectly via Mr. Weiner’s position as President of St. Joseph Mercy Oakland Hospital in terms of direct and indirect compensation, department budgets and staffing, and acquisition of medical equipment, medical devices, computer systems or additional appointments to Michigan Stroke Network.” (Am. Compl. ¶ 45.) Plaintiff asserts that the alleged conflict of interest was one “of the highest order and obviously precluded under 45 C.F.R. § 94.” (Am. Compl. ¶ 46; *see also id.* ¶¶ 138, 229.)

Plaintiff, however, has not pled a cause of action under 45 C.F.R. § 94 (even assuming, again, that a private right of action exists). Plaintiff appears to quote 45 C.F.R. § 94 as follows:

A principal investigator for an IRB approved clinical research “project” involving human subjects, who is also physician to a patient who is participant or a candidate to become a participant in the aforementioned research “project” has an inherent and

⁵The Court notes that the Department of Health and Human Services has promulgated institutional review board regulations that are, for purposes of this case, virtually identical to those promulgated by the FDA. *Compare, e.g.,* 21 C.F.R. § 56.111 *with* 45 C.F.R. § 46.111. In fact, Plaintiff often cites 45 C.F.R. § 46 and acknowledges that “21 C.F.R. § 56.111 and 45 C.F.R. § 46.111 are mere images of each other.” (Am. Compl. ¶ 160.) This is relevant because Courts have also found that the regulations set forth at 45 C.F.R. § 46 do not create a private right of action. *Robertson ex rel. Robertson v. McGee*, No. 01CV60, 2002 WL 535045, at *3 (N.D. Okla. Jan. 28, 2002) (“[T]he Court finds that there is no private right of action under 21 C.F.R. §§ 210, 211 and 45 C.F.R. Part 46.”); *see also Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286, 1289-90 (W.D. Wash. 2002).

insurmountable conflict of interest in that as physician he/she must act with duty of care placing patient needs and safety as first priority, yet as principal investigator, he/she has a vested interest in the outcome and success of the research project.

(Am. Compl. ¶ 138.) But the Court has reviewed the 2006 and 2007 versions of 45 C.F.R. § 94.1 through § 94.6 and this language is not present in those regulations. *See generally* 45 C.F.R. §§ 94.1-94.6 (West 2006, 2007). More importantly, 45 C.F.R. § 94.1 *et seq.* applies to institutions that “seek[] [Public Health Service] funding for research,” have submitted a proposal for a research contract to the Public Health Service, and that have “assume[d] the legal obligation to carry out the research required under the contract.” 45 C.F.R. §§ 94.2, 94.3. Plaintiff has not pled any Public Health Service contract involving the Wingspan Stent and St. John IRB or Henry Ford IRB.

In sum, although this Court believes that the applicable statute of limitations bars Plaintiff’s entire complaint, the Court alternatively recommends that Counts I, II, V, and VI be dismissed for failure to state a claim upon which relief may be granted because (1) Plaintiff has not adequately pled how the cited Medicare standards apply to institutional review boards such as Defendants, and (2) the regulations that are applicable to IRBs do not create a private right of action.

D. Plaintiff’s Fed. R. Civ. P. 56(d) Affidavit Does Not Preclude Dismissal

Plaintiff has filed what appears to be a Fed. R. Civ. P. 56(d) affidavit. (*See* Dkt. 48, Aff. of Mark Zanecki.) He says that he cannot present facts necessary to oppose Henry Ford IRB’s “motion for summary judgment” without certain discovery. (*Id.*) But Henry Ford IRB has not moved for summary judgment. It has moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). (*See* Henry Ford IRB’s Mot. to Dismiss at 2-3.) Further, the Court has applied Rule 12(b)(6) standards. Accordingly, Plaintiff’s Rule 56(d) affidavit does not preclude dismissal of Henry Ford IRB.

E. St. Joseph IRB's Motion for Summary Judgment Should Be Denied Without Prejudice

St. Joseph IRB's Fed. R. Civ. P. 56 motion argues that Plaintiff's claims against St. Joseph IRB are barred by res judicata, the settlement agreement executed in the state-court case, or both. Given that this Court's reasons for recommending dismissal of Henry Ford IRB apply with equal force to St. Joseph IRB, it is unnecessary to reach St. Joseph IRB's preclusion and settlement-release arguments. On the other hand, because St. Joseph IRB has neither moved pursuant to Rule 12(b)(6) nor joined Henry Ford IRB's motion, the Court will not dismiss St. Joseph IRB on grounds it has not raised under a procedural device it has not invoked. Accordingly, the Court will recommend that St. Joseph IRB's motion for summary judgment be denied without prejudice with leave granted to St. Joseph IRB to file a motion to dismiss for the reasons set forth in this Report and Recommendation.

III. CONCLUSION AND RECOMMENDATION

For the foregoing reasons, this Court recommends that Henry Ford Health System IRB #1's Motion to Dismiss (Dkt. 47) be GRANTED and Plaintiff's Amended Complaint against Henry Ford Health System IRB #1 be DISMISSED. The Court further recommends that St. Joseph Mercy Oakland - Trinity Health System IRB #1's Motion for Summary Judgment (Dkt. 9) be DENIED WITHOUT PREJUDICE, but that St. Joseph IRB be granted leave to file a motion to dismiss for the reasons set forth in this Report and Recommendation.

IV. FILING OBJECTIONS

The parties to this action may object to and seek review of this Report and Recommendation within fourteen (14) days of service of a copy hereof as provided for in 28 U.S.C. § 636(b)(1). Failure to file specific objections constitutes a waiver of any further right of appeal. *Thomas v. Arn*, 474 U.S. 140 (1985); *Frontier Ins. Co. v. Blaty*, 454 F.3d 590, 596 (6th Cir. 2006); *United States v. Sullivan*, 431 F.3d 976, 984 (6th Cir. 2005). The parties are advised that making some objections, but failing to raise others, will not preserve all the objections a party may have to this Report and Recommendation. *McClanahan v. Comm'r Soc. Sec.*, 474 F.3d 830 (6th Cir. 2006) (internal quotation marks omitted); *Frontier*, 454 F.3d at 596-97. Objections are to be filed through the Case Management/Electronic Case Filing (CM/ECF) system or, if an appropriate exception applies, through the Clerk's Office. *See* E.D. Mich. LR 5.1. A copy of any objections is to be served upon this magistrate judge but this does not constitute filing. *See* E.D. Mich. LR 72.1(d)(2). Once an objection is filed, a response is due within fourteen (14) days of service, and a reply brief may be filed within seven (7) days of service of the response. E.D. Mich. LR 72.1(d)(3), (4).

s/Laurie J. Michelson
LAURIE J. MICHELSON
UNITED STATES MAGISTRATE JUDGE

Dated: January 17, 2013

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing order was served on the attorneys and/or parties of record by electronic means or U.S. Mail on January 17, 2013.

s/Jane Johnson
Deputy Clerk